

Title: Strategic Training to Optimize Neurocognitive Functions in Older Adults

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The University of Texas Southwestern Medical Center  
Parkland Health & Hospital System  
Children's Medical Center  
Retina Foundation of the Southwest  
Texas Scottish Rite Hospital for Children  
Texas Health Presbyterian Hospital Dallas

## CONSENT TO PARTICIPATE IN RESEARCH

Title of Research: **Strategic training to optimize neurocognitive functions in older adults Study**

Funding Agency/Sponsor: The National Institutes of Health (NIH)

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### Key Information about this Study:

The purpose of this research study is to determine the effectiveness attention training for older adults to increase how long memories can be kept. Older adult participants will play games-based simulations designed to increase memory retention, undergo MRI scans, and undergo 3 behavioral assessments. The memory training will last about 19 hours over an 8 week period.

The greatest risks of this study include the possibility of loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.

### Instructions:

Please read this consent form carefully and take your time making a decision about whether to participate. As the researchers discuss this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of the study, risks, inconveniences, discomforts, and other important information

about the study are listed below. If you decide to participate, you will be given a copy of this form to keep.

**Why is this study being done?**

This study is being done to evaluate the effects of cognitive training on the cognitive abilities, brain structure and function, and quality of life of individuals with age-related cognitive decline as compared to a computer-based series of games.

**Why am I being asked to take part in this research study?**

You are being asked to take part in this study because you are a healthy adult between the ages of 55-85 (for older adults).

**Do I have to take part in this research study?"**

No. You have the right to choose whether you want to take part in this research study. If you decide to participate and later change your mind, you are free to stop participation at any time.

If you decide not to take part in this research study, it will not change your legal rights or the quality of health care that you receive at this center.

**How many people will take part in this study?**

About 51 people will take part in this study at UT Southwestern.

**What is involved in the study?**

If you volunteer to take part in this research study, you will be asked to sign this consent form and will have the following tests and procedures. Some of the procedures may be part of your standard medical care, but others are being done solely for the purpose of this study.

Screening Procedures

To help decide if you qualify to be in this study, the researchers will ask you questions about your health, including medications you take and any surgical procedures you have had.

You may also have to fill out certain forms or have the following exams, tests or procedures:

- Demographic information and health history questionnaire
- Montreal Cognitive Assessment (MOCA)
- Mini-mental Status Examination (MMSE)

Group Assignment

If after the pre-screening and the Mock Scan sessions, a volunteer meets the inclusion and exclusion criteria, he or she will be randomized into one of the three training arms. This assignment will be based on a random computerized allocation



plan, where the average cognitive frailty, age, education and gender distribution will be maintained to be equivalent across the three arms. By randomly assigning participants in the training arms and by assessing outcomes by blinded experimenters, we will avoid selection bias and outcome assessment bias. The participant will need to be randomized to a training arm prior to any baseline assessments.

### Procedures and Evaluations during the Research

The following table summarizes what is included in the study and how many visits you need to make to our lab:

Appointment	Time	Location	Brief description
Visit 1: Orientation, cognitive screening, and mock MRI	1.5 hr	AIRC (UTSW)	Orientation to the study, health history screening, and mock MRI. After this visit, if you are eligible to continue in the study, you will return for further sessions.
Visit 2: Neuropsychological	3.5 hr	Center for Vital Longevity (CVL)	Computer and paper-pencil tasks
Visit 3: MRI	2 hr	AIRC (UTSW)	MRI scan
8 week cognitive training	Week 1: 1.5 hr training in CVL Week 2-8: 1 hr training in lab; 2x45 min training in home	CVL and Participant's Home	You will complete these training sessions at your leisure in your home
Visit 4: Neuropsychological	3.5 hrs	CVL	Computer and paper-pencil tasks
Visit 5: MRI	2 hr	AIRC (UTSW)	MRI scan
Visit 6: Neuropsychological	3.5 hrs	CVL	Computer and paper-pencil tasks

Each of the appointments in the table are described in more detail below:

**Visit 1: Orientation and cognitive screening.** During this screening and orientation session, we will introduce you to the study and ask you to complete a survey to assess whether you qualify to continue in the study. You will be asked to complete a demographic and detailed health history questionnaire. The demographic survey asks for information about you (such as date of birth, race/ethnicity, sex, native language, educational background, occupation), about physical characteristics (handedness, hearing, color blindness), about your

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medications, hospitalizations, and medical conditions or medical diagnosis. We will also ask for your contact information and whether you agree to be contacted about other studies in this lab.

The last part of this session will be a brief "Mock MRI." Since a later session of this experiment includes a scan of your brain in a Magnetic Resonance Imaging scanner, we would like to take some time in your first visit to make sure you will be comfortable in an MRI scanner. The Mock MRI will give you a chance to experience what an actual MRI will be like and to ask any questions you have before deciding whether you are comfortable participating in the MRI part of the study. During this part of the visit, we will also discuss if you are able to go into an MRI scanner. Individuals with metal in his/her body should not go into an MRI scanner.

**Visits 2, 4, and 6: Neuropsychological assessment-** You will be asked to complete one neuropsychological testing session before the intervention, one after the intervention, and one final session 6 months after completing the training program. You will be asked to perform a variety of computerized and paper pencil tasks that measure cognitive, learning, and motor skills. You will be given breaks between tests.

**Visits 3 and 5: MRI Scan-** You will be asked to undergo an MRI scan. This set of scans will require you to lie as still as you can while resting quietly.

Details: Upon arrival, you will be greeted by a lab researcher. They will escort you to the waiting room and guide you through the MRI screening procedures and familiarization with the tasks you will do in the MRI scanner. Once ready to start the experiment, you will be asked to remove all metal objects. If your clothes have zippers or metal buttons (or similar) that would interfere with the pictures of your brain, we may ask you to change into hospital clothing that does not contain any metal.

An MRI scanner takes images of your brain by sending out a magnetic field and radio waves. Because the MRI scanner contains a very strong magnet, you may not be able to have the MRI if you have certain kinds of metal in your body (for example, a heart pacemaker, a metal plate, and certain types of heart valves or brain aneurysm clips). Someone will ask you questions about this before you have the MRI. Let us know if you have had surgery of any kind.

In particular, you should not participate in this study if you have any of the following in your body:

Pacemaker  
Coronary Stent  
Defibrillator



## Neurostimulator

There are a number of conditions that will prevent you from having the MRI, we will review these with you to see if you can have the MRI.

Once cleared to have an MRI in this study, you will enter the MRI room with your experimenter and MRI technicians. The MRI scanner is a large machine that contains a hollow tube. You will be asked to lie on your back on a special table that slides into the tube. For this study a coil will be positioned around your head. The head coil is similar in shape to a helmet. The coil is the part of the machine that receives the MR signal and allows images to be captured. The sides of the tube will be fairly close to your body and the scanner makes a loud hammering noise while you are inside. You will be able to talk to people in the room through a speaker system. We will monitor you closely while you are inside the scanner. You will also be given earplugs to wear. The earplugs reduce the sharpness of the banging noise the MRI machine makes. However, you will still be able to hear us talk to you, and you will also be able to talk to us at any time. We will also give you a squeeze ball to press in case of an emergency. This sets off an alarm that notifies the technologist that you need help.

Next, the bed will be moved into the magnet. The MRI technician will talk to you throughout the study and let you know how you are doing and what to expect next. Since we are interested in how your brain is functioning at rest, you will complete several blocks that require resting quietly while being scanned. We will use a mirror mounted on the head coil so that you can see visual stimuli and special noise-canceling headphones to hear audio sounds. You will be able to communicate with the technologist using a microphone that is built into the headphones. During some scans we may also collect basic physiological signals, such as your heart rate and breathing. This will require you to wear a monitoring device on your finger or a respiratory belt around your chest. You will be informed prior to the scan of the exact procedure that will occur during the MRI. If you become uncomfortable and wish to stop the examination at any time, you may inform the technologist, and the study will be terminated and you will be moved out of the magnet. The technologist will also let you know when the images are being acquired. You will need to hold very still during that time. You should hold relatively still in between images as well. You will be in the magnet for approximately 50 minutes. For most of this time you will not have to actively do anything except lie quietly while we collect images of your brain. When the study is complete, you will be moved out of the magnet. You should get up slowly to allow your body to get use to moving and being vertical again.

After the completion of your MRI scan, a member of the research team will electronically move the images that were taken to another secure computer. Any information that could be used to identify you as the subject of these images will be replaced with a unique ID code. The images and information about how they were taken will be stored in a central database so that other researchers can use them to evaluate how MR imaging could be used for their research projects. These investigators must

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submit a formal written request to the research team for approval to have access to the data. The data may then be copied electronically to their laboratory's computers. Your name and corresponding code will be kept in a locked cabinet that can only be accessed by the research team. The other investigators who have requested to use the images will not have access to the correspondence between the unique ID code and your name.

The MRI images for this study are not being used to evaluate your health. The images obtained for this study are for specific research purposes and are not being used to find medical abnormalities. These images will not routinely be reviewed by a radiology physician to diagnose existing abnormalities.

It is possible that this study will identify information about you that was previously unknown, such as disease status or risk. There are no plans to provide this information to you or your physician.

**8-week cognitive training intervention-** You will be asked to complete an 8-week cognitive training intervention that includes in-lab and at home sessions of a working memory task.

The psychological assessments in this study are designed for research, not for medical purposes. They are not useful for finding problems or diseases. Even though the researchers are not looking at your results to find or treat a medical problem, you will be told if they notice something unusual. You and your regular doctor can decide together whether to follow up with more tests or treatment. Because the assessments done in this study are not for medical purposes, the research results will not be sent to you or to your regular doctor.

#### **How long can I expect to be in this study?**

If you agree to take part in this study, your involvement in the first phase will last for approximately 3 months. Overall, there will be 14 visits, which include a consent and orientation session; 2 pre-intervention visits to measure cognitive functions and to take an MRI scan; 8 training sessions; 2 post-intervention visits to measure training-related changes in cognitive functions and brain (through MRI scan), and one final 6-month follow-up session to measure changes in cognitive functions. You will be asked to complete a 45 minute session at home with the training software 2 times per week for 7 consecutive weeks.

You can choose to stop participating for any reason at any time. However, if you decide to stop participating in the study, we encourage you to tell the researchers. You may be asked if you are willing to complete some study termination tests.

#### **What are the risks of the study?**

You may experience one or more of the risks indicated below from being in this study.



You may experience some discomfort during the assessments. Assessments may be fatiguing for some individuals. To minimize the potential discomfort, breaks are encouraged.

You may experience some discomfort during program use such as fatigue, mood complaint, headache, tremor, eye strain, neck/shoulder discomfort, leg/hip discomfort, arm/wrist discomfort, back discomfort, headache and sleep difficulty. If you experience any discomfort, it is encouraged that you take a break from using the program.

You may be uncomfortable inside the MRI scanner if you do not like to be in closed spaces ("claustrophobia"). During the procedure, you will be able to talk with the MRI staff through a speaker system. You can tell them to stop the scan at any time.

The MRI scanner produces a loud hammering noise, which has produced hearing loss in a very small number of patients. You will be given earplugs to reduce this risk.

A metal object flying through the air toward the magnet and hitting you presents the greatest risk associated with MRI. To reduce this risk, we require that all people involved with the study undergo MRI safety training and remove all metal from their clothing and pockets during the MRI session. No metal objects will be brought into the magnet room while you are inside the room. In addition, the door to the room remains closed throughout the study so that no one can accidentally bring a metal object into the room.

There are no known risks associated with limited exposure to magnetic fields. Magnets of this strength have been in use for medical imaging for over 15 years. However, we will keep a record of the length of time you were in the magnet as well as the amount of radio waves used during that time.

There is no known risk associated with MRI to the unborn child. In fact, MRI is often used to look at problems in unborn children. However, we cannot rule out the possibility that such a risk will be discovered in the future. Its effect on the unborn child is not known. Therefore, if you are a woman of childbearing age, you should not participate if you are pregnant, trying to become pregnant, or currently breastfeeding. If you are not sure of your status, we can schedule a serum pregnancy test for you.

#### Loss of Confidentiality

Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

#### Other Risks



There may possibly be other side effects that are unknown at this time. If you are concerned about other, unknown side effects, please discuss this with the researchers.

**How will risks be minimized or prevented?**

To address the potential risk of boredom, fatigue or frustration during the behavioral tasks, we will provide frequent breaks to participants, including opportunity to get water and stretch their legs.

To address the risk that subjects could feel uncomfortable answering questions, we will remind participants that all questions are voluntary. It may be the case that they are ineligible if they are not comfortable answering some questions that are critical to ensuring their safety and meeting the goals of the study. In this case participants will be reminded that participation is voluntary and we would be happy to contact them for future studies that they may find more comfortable participating in.

To address the potential for anxiety in the MRI scanner, we will conduct a "Mock MRI" before the actual MRI. This session allows the participant to experience what it is like to lie in the magnet but without the pressure and time constraints of the actual scanner session. Importantly, this allows us to anticipate and prevent participant anxiety as much as possible during the real MRI.

To address the potential for discomfort during the MRI session, we will work with the participant during the Mock MRI to arrive at a comfortable lying position (e.g., with or without a pillow under their legs and how much cushioning they prefer if they would like a pillow). We will also utilize the Mock MRI session to screen out anyone who does not fit comfortably in the bore of the scanner, such as their shoulders or stomach pressing against the walls of the bore. During the MRI itself, we will regularly check in with the participant about their comfort, so that we can make adjustments in their positioning when needed. Participants who are uncomfortable with the MRI scan do not have to complete the MRI visit if they fit all other criteria to participate in the rest of the study.

To address any potential for hearing loss, participants will wear earplugs during all scanning.

To address the risk of flying metal objects, we require that all people involved with the study remove all metal from their clothing and pockets. No metal objects will be brought into the magnet room while participants are inside the room. In addition, the door to the room remains closed throughout the study so that no one can accidentally bring a metal object into the room.

To minimize the fatigue, the program is designed to be entertaining and enjoyable. In addition, training sessions may be paused at any time and participants are encouraged to take breaks.

To address potential for loss of confidentiality, we will:

- store paper/pencil data in secure, locked file cabinets, accessible only to lab personnel
- computer data will be stored on lab testing PCs that are password protected and only accessible to lab personnel
- all data will be stored with only subject ID's attached, in a separate location from the consent and demographic forms
- subject ID's will be assigned following informed consent

### **What will my responsibilities be during the study?**

While you are part of this study, the researchers will follow you closely to determine whether there are problems that need medical care. It is your responsibility to do the following:

- Ask questions about anything you do not understand.
- Keep your appointments.
- Follow the researchers' instructions.
- Let the researchers know if your telephone number or address changes.
- Store study materials in a secure place at home away from anyone who is unable to read and understand labels, especially children.
- Tell the researchers before you take any new medication, even if it is prescribed by another doctor for a different medical problem or something purchased over the counter.
- Tell your regular doctor about your participation in this study.
- Report to the researchers any injury or illnesses you suffer during the study, even if you do not think they are related.

### **If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?**

Yes. You will be told if any new information becomes available during the study that could cause you to change your mind about continuing to participate or that is important to your health or safety.

### **What should I do if I think I am having problems?**

If you have unusual symptoms, pain, or any other problems while you are in the study, you should report them to the researchers right away. Telephone numbers where they can be reached are listed on the first page of this consent form.

If you have a sudden, serious problem, like difficulty breathing or severe pain, go to the nearest hospital emergency room, or call 911 (or the correct emergency telephone number in your area). Tell emergency personnel about any medications you are taking, including any medications you are taking for this study.

### **What are the possible benefits of this study?**



If you agree to take part in this study, there may or may not be direct benefits to you. The researchers cannot guarantee that you will benefit from participation in this research.

We hope the information learned from this study will benefit others in the future. Information gained from this research could benefit individuals with age-related cognitive decline.

**What options are available if I decide not to take part in this research study?**

This is not a treatment study. You do not have to be part of it to get treatment for your condition.

**Will I be paid if I take part in this research study?**

Yes, you will be issued a UT Dallas Greenphire ClinCard, which can be used as a credit or debit card. Compensation will be credited to the card after completion of each session. Your name, address, and date of birth will not be shared with a third-party, we will assign you a random birthdate which you can use to set up a pin code for your card. Participants will be compensated in the following rate:

Sessions	Time (hour)	\$/hour	Total Cost(\$)	Weeks
Pre-screening	1	15	15	Week 1
Assessment A	3.5	15	52.5	Week 1
Mock Magnet Scan	1	15	15	Week 1 or 2
MRI Pre-test Scan	1	45	45	Week 3
In-Lab Training	8.5	15	127.5	Week 3-10
At-Home Training	10.5	10	105	Week 5 - 10
MRI Post-test Scan	1	45	45	Week 11
Assessment B	3.5	15	52.5	Week 11
Assessment C+				
Completion Bonus (\$90)	3.5	15	52.5	Week 37/38
<b>TOTAL</b>	<b>33.5</b>		<b>\$600</b>	

**Will my insurance provider or I be charged for the costs of any part of this research study?**

No. Neither you, nor your insurance provider, will be charged for anything done only for this research study (i.e., the Screening Procedures, Experimental Procedures, or Follow-up Procedures described above).

However, the standard medical care for your condition (care you would have received whether or not you were in this study) is your responsibility (or the responsibility of your insurance provider or governmental program). You will be charged, in the standard manner, for any procedures performed for your standard medical care.

**What will happen if I am harmed as a result of taking part in this study?**

It is important that you report any illness or injury to the research team listed at the top of this form immediately.

Compensation for an injury resulting from your participation in this research is not available from the University of Texas Southwestern Medical Center at Dallas or University of Texas at Dallas.

You retain your legal rights during your participation in this research

**Can I stop taking part in this research study?**

Yes. If you decide to participate and later change your mind, you are free to stop taking part in the research study at any time.

If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

**If I agree to take part in this research study, can I be removed from the study without my consent?**

Yes. The researchers may decide to take you off this study if:

- The researchers believe that participation in the research is no longer safe for you.
- The researchers believe that other treatment may be more helpful.
- The sponsor or the FDA stops the research for the safety of the participants.
- The sponsor cancels the research.
- You are unable to keep appointments or to follow the researcher's instructions.

**Will my information be kept confidential?**

**How will my information and/or tissue samples be used?**

With appropriate permissions, your samples and collected information may also be shared with other researchers here, around the world, and with companies.

By agreeing to participate in this study, your information or tissue samples could be used for future research studies or sent to other investigators for future research studies without additional consent from you. The information that identifies you will first be removed from your information or tissue samples. If you do not want your



information or tissue samples to be used for future research studies without your consent, you should not participate in this study.

Your data may be shared with the following organizations that may look at and/or copy your data for research, quality assurance, and data analysis:

- The University of Texas at Dallas; and
- The UT Southwestern Institutional Review Board

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

In addition to this consent form, you will be asked to sign an "Authorization for Use and Disclosure of Protected Health Information." This authorization will give more details about how your information will be used for this research study, and who may see and/or get copies of your information.

**Are there procedures I should follow after stopping participation in this research?**

If you decide to leave the study early, we will ask you to come to a close out visit to discuss your reasons for withdrawing. This information will help us improve our adherence when designing future studies. Please also note that if you withdraw from the study during the intervention, you will not be compensated for any intervention sessions.

**Whom do I call if I have questions or problems?**

For questions about the study, contact Dr. Chandramallika Basak at 972-883-3724 during regular business hours and at 217-778-5671 after hours and on weekends and holidays.

For questions about your rights as a research participant, contact the UT Southwestern Institutional Review Board (IRB) Office at 214-648-3060.

**SIGNATURES:**

**YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.**

Your signature below certifies the following:

- You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.

- You understand that you are not giving up any of your legal rights.

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Name of Participant (Printed)

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Signature of Participant

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Date

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Time

AM / PM

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Name of Person Obtaining Consent (Printed)

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Signature of Person Obtaining Consent

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Date

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Time

AM / PM